510K Summary

K062593

Prepared: 8/29/2006

Submitted by: Evy K. Johnson
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NOV 2 2 2006

Establishment Registration Number: 2032652

Contact Person: Dr. Carter Grandjean, Director R&D

Proprietary Name: Cardiac Markers Control and Calibration Verification Set

Common Name: Cardiac Markers Control and Calibration Verifier Controls

Classification Name: Multi Analyte Controls, All Kinds (assayed and unassayed) 75 JJY

Substantial Equivalence:

The Compass Bioscience Cardiac Markers Control and Calibration Verification Set are supplied liquid in three or 4 levels and consist of a human plasma matrix containing preservatives to which reagent grade chemicals and human source antigens and enzymes have been added at different concentrations to achieve the levels. Assayed values are determined from in house and interlaboratory data.

The Compass Bioscience controls and calibration verifiers are substantially equivalent to other such controls and verifiers in general use, such as the **Triage® Profiler S.O.B.™ (Shortness of Breath) Control** and the **Triage® Profiler S.O.B.™ (Shortness of Breath) Calibration Verification Controls** which are supplied liquid in a two level control set and five level calibration verification set as a human EDTA plasma matrix with human source constituents and pure chemicals added by the manufacturer.

Description:

Compass Bioscience Cardiac Markers Controls are supplied in three levels, 2 x 1 mL each level per box and as a four Level Calibration Verification set, 2 x 1 mL each level per box. The controls are supplied as a ready-to-use frozen liquid, requiring no reconstitution or dilution. They are prepared in a human EDTA plasma matrix fortified to target levels with human source material and reagent grade chemicals added at different concentrations to achieve the levels. Sodium Azide <0.1% has been added as preservative to inhibit microbial growth.

Intended Use:

The Compass Bioscience Cardiac Markers Controls are intended for use as quality control materials to assess the accuracy and precision of assay procedures for the analytes included in the control. The Compass Bioscience Cardiac Marker Calibration Verification Set is used to verify the calibration of various test methods over the measurable range of the test.

Technological Characteristics Compared to Predicate Devices:

The Compass Bioscience control products employ a similar matrix and constituent formulation to the equivalent predicate device listed above: human plasma matrix fortified with human source material,

reagent grade chemicals and azide as a preservative. The Compass Bioscience Control and Calibration Verification Set also have similar storage and stability requirements as the equivalent devices.

Performance Characteristics:

The closed vial stability claim made for this product is 1 year when stored at -20° C, based on accelerated stability studies.[2] The Cardiac Markers control was stored at 2-8°C to simulate 1 year storage -20°C. An increase or decrease of >10% of analyte recovery compared to the initial test value ± the highest allowable instrument/reagent imprecision was used as the analyte failure criterion for determining shelf-life. Real time stability testing is ongoing on multiple lots of product.

The closed and opened vial stability claim for this product when stored at 2-8° C is 30 days for CK-MB and Myoglobin and 14 days for Troponin I and BNP. Real time testing was used to determine the closed and open vial refrigerated shelf life. The Cardiac Markers Control was stored at 2 - 8° C and the recovery (vs. day 0) was measured in intervals of 7 days. The product passed stability if its recovery was within ±(10% + % CV_{method}) after 44 days of storage at 2- 8°C.

Multiple lots of product were tested with no significant difference in performance.

The equivalent predicate device, Triage® Profiler S.O.B.™ Control claims a 2 year shelf life for storage at -20°C and a single use. The Bayer Healthcare LLC Liquid Cardiac Markers Plus Control claims a 20 day opened/closed vial stability at refrigerated (2-8°C) storage.

Assayed Values

Assay values for the package inserts were established from assays performed in the Compass Bioscience laboratory using three Triage® MeterPlus readers with the Triage® Profiler S.O.B.™ Panel tests, the Triage® CardioProfiler Panel, and the Triage® Cardiac Panel, and from interlaboratory data using instrument manufacturers' reagents. Mean values for the listed lots of controls were calculated from multiple instruments and reagent lots available at the time of assay. Ranges were determined based on 2 SD – 3SD of the overall mean values from stability and interlaboratory data.

[2] L. Kennon, Stability Prediction Model, Journal of Pharmaceutical Sciences 53:7, 815-818, 1964.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 2 2 2006

Ms. Evy K. Johnson
Compass Bioscience
1850 Evergreen Street
Duarte, CA 91010

Re: k062593
Trade/Device Name: Cardiac Markers Control
Cardiac Markers Calibration Verification Control Set
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJY
Dated: August 30, 2006
Received: September 6, 2006

Dear Ms. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062593

Device Name: Cardiac Markers Control
Cardiac Markers Calibration Verification Control Set

Indications For Use:

The Compass Bioscience Cardiac Markers Controls are to be used as a quality control material to assess the accuracy and precision of laboratory test methods used to measure the antigens and enzymes contained in the control. It is intended to validate the measurement of these analytes in patient samples.

Three levels of control are provided to allow the performance of the analyte test methods to be monitored within the clinically significant range.

The Compass Bioscience Cardiac Marker Calibration Verification Control Set is used to verify the calibration of various test methods over the measurable range of the test.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol Benson
Division Sign-Off

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Office of In Vitro Diagnostic Device
Evaluation and Safety

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